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1614

DI-5954 (BXTD 9004.6)  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Somers et al.  
Serial No. 10/683,549  
Filed October 10, 2003  
Confirmation No. 2624

Art Unit 1614

For STABILIZATION OF PHARMACEUTICAL PROTEIN FORMULATIONS WITH  
SMALL PEPTIDES

January 26, 2004

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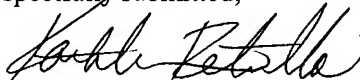
SIR:

**INFORMATION DISCLOSURE STATEMENT**

\* In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the Pre-OG notice of July 11, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Applicants submit herewith copies of the foreign patent documents/literature references.

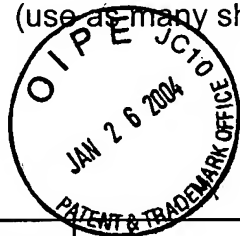
This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicants believe that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required. However, if an Office action was issued prior to the date of mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge any required fees regarding this Information Disclosure Statement to Deposit Account No. 19-1345.

Respectfully submitted,

  
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<b>PTO/SB/08A</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/683,549
				Filing Date	October 10, 2003
				Confirmation Number	2624
				First Named Inventor	Somers et al.
				Group Art Unit	1614
				Examiner Name	Unknown
Sheet	1	of	2	Attorney Docket No.	DI-5954 (BXTD 9004.6)



U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	1	4,703,008		Fu-Kuen Lin	10-27-1987
	2	4,992,419		Woog et al.	02-12-1991
	3	5,141,905		Rosen et al.	08-25-1992
	4	5,366,875		Wozney et al.	11-22-1994
	5	5,661,125		Thomas Wayne Strickland	08-26-1997
	6	5,688,679		Jerry S. Powell	11-18-1997
	7	5,705,482		Christensen et al.	01-06-1998
	8	5,919,757		Michaelis et al.	07-06-1999
	9	6,277,367	B1	Yamazaki et al.	08-21-2001
	10	US 2003/0092622	A1	Sato et al.	05-15-2003

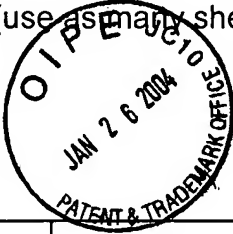
FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)			
	11	PCT	WO 01/24814	A1	Chiron Corporation	04-12-2001	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

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<b>PTO/SB/08A</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)  				<b>Complete if Known</b>	
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Sheet	2	of	2	Attorney Docket No.	DI-5954 (BXTD 9004.6)

	12	PCT	WO 02/14356	A2	Claudia Althoff	02-21-2002	
	13	PCT	WO 02/014356	A3	Elanex Pharma (IOM) Ltd.	02-21-02	

### OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	14	DUGAS, H., et al., "Chemical Synthesis of Proteins," Bioorganic Chemistry of the Amino Acids, 1981, pp. 54-92, Springer-Verlag, New York.	
	15	HARRIS, S., et al., "Effects of Transforming Growth Factor $\beta$ on Bone Nodule Formation and Expression of Bone Morphogenetic Protein 2, Osteocalcin, Osteopontin, Alkaline Phosphatase, and Type I Collagen mRNA in Long-Term Cultures of Fetal Rat Calvarial Osteoblasts," Journal of Bone and Mineral Research, 1994, pp. 855-863, Vol. 9, No. 6, Mary Ann Liebert, Inc.	
	16	NIMTZ, et al., "Structures of Sialylated Oligosaccharides of Human Erythropoietin Expressed In Recombinant BHK-21 Cells," Eur. J. Biochem., 1993, pp. 39-56, Vol. 213.	
	17	STORRING, P., et al., "Epoetin Alfa and Beta Differ in Their Erythropoietin Isoform Compositions and Biological Properties," British Journal of Haematology, 1998, pp. 79-89, Vol. 100.	
	18	SYTKOWSKI, A., et al., "Biological Activity and Structural Stability of N-Deglycosylated Recombinant Human Erythropoietin," Biochemical and Biophysical Research Communications, 1991, pp. 698-704, Vol. 176, No. 2.	
	19	TSUDA, E., et al., "The Role of Carbohydrate in Recombinant Human Erythropoietin," Eur. J. Biochem., 1990, pp. 405-411, Vol. 188.	
	20	URIST, M., "Bone: Formation by Autoinduction," Science, 1965, pp. 893-899, Vol. 150.	
	21	WOZNEY, J., et al., "Novel Regulators of Bone Formation: Molecular Clones and Activities," Science, 1988, pp. 1528-1534, Vol. 242.	

Examiner Signature		Date Considered	
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